Date: 5/6/2011
GAIN Report Number: E60030

EU-27

Post: Brussels USEU

Nanotechnology in Food - current status in the EU

Report Categories:
Trade Policy Monitoring
FAIRS Subject Report
Biotechnology and Other New Production Technologies

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Report Highlights:
This report explains what nanotechnology is, how it is used, what the concerns are and how it is or will be assessed and regulated in the EU with regard to its use in food.

General Information:

1. What is nanotechnology? - Nanotechnology is the science and technology at the nano-scale of atoms and molecules and refers to the controlled production of new materials with dimensions in the range of nanometers or dimensions thousands of times smaller than the diameter of a human hair and about the size of a small molecule. Nanoparticles have a considerably greater surface area to mass ratio than their larger counterparts which can alter physical and chemical properties such as reactivity and surface charge. In general, nanotechnology has the potential to reduce waste across the whole life-cycle of products because less raw materials will be used for greater performance. The term nanotechnology is used as a collective term, for the various branches of nanosciences and nanotechnologies.

Some products based on nanotechnology have already been marketed, such as medical products, pharmaceuticals, scratch-free paint, wrinkle and stain resistant fabrics and cosmetics, such as sun creams. As the performance of materials under extreme conditions can be improved significantly, nanotechnology can advance developments in aeronautics and space industries.

Nano in food - Nanotechnology can be used in food production to enhance the taste, color, flavor, texture and consistency of a variety of foods. Only few applications are available in the EU within the food area, mostly related to **supplements and packaging**. Most applications are not even referred to as nano, since they were assessed and approved under the existing regulatory framework. A major future challenge in the food area would be the production of healthy food products with less fat, salt, preservatives.

Examples:

- Nano-encapsulated nutrients/supplements demonstrate an enhanced bio-availability and therefore an increased efficiency.
- Nano(bio)sensors incorporated in packaging monitor the condition of the packaged foodstuffs and detect contaminants. The enhanced mechanical and thermal properties ensure better protection of food from exterior, thermal, chemical or microbiological effects resulting in extended shelf life.
- Polymer nanocomposites used for packaging and wrapping offer adjustable gas permeability which can help to better protect food. Clay nanoparticles embedded between PET layers are used to improve plastic packaging for food products. The particles are dispersed throughout the plastic and are able to block oxygen, carbon dioxide and moisture from reaching fresh meats or other foods. The nanoclay also makes the plastic lighter, stronger and more heat-resistant.
- Anti-microbial packaging materials containing nanosilver demonstrate anti-microbial properties.
- Packaging with self cleaning surfaces. Dirt-repellent coatings prevent the invasion of microorganisms.

Consumer perception - Nanotechnology may be a difficult concept for the public to grasp, because of its complexity and its invisible scale. Additionally, food applications are very sensitive to the general public. According to a recent report of the Food Standard Agency (FSA) regarding the consumer perception on nano, acceptance around the use of nanotechnology is conditional. Consumers are more positive about the use of nanotechnology to reduce the salt or fat content of foods without adversely affecting the taste or texture, while they are less favorable towards the use of nanotechnology to develop new flavors and textures. The research also revealed that consumers are relatively more open to the use of nanotechnology in food packaging and readily identified the potential benefits of extended shelf life and waste reduction. The general public

needs to be more engaged on nanotech**,** including transparency on new developments and the availability of information. In doing so, European consumers would be more likely to appreciate the benefits and use of nanotechnology in food. "Communicating Nanotechnology" published by DG Research, analyses how nanotechnology should be communicated to the general public.

2. Challenges for risk assessment and risk management

Concerns about nanotechnology in food - The specific properties related to the size of nanotechnology make a proper risk assessment difficult. There are concerns about nanomaterials being released during a product's lifecycle. Nanoparticles have the potential to remain and accumulate in the environment and possibly in the food chain as well. The small dimensions of nanoparticles means they can reach location in the human body not normally accessible to larger counterparts. Insoluble nanoparticles may cross cellular barriers and accumulate in the human body, e.g. brain. When focusing on risk assessment of nanofoods, one of the major issues is the lack of routine methods to assess food or feed tissues and that no information is available on overall exposure. The ability to predict long-term health effects arriving from nanotechnology in food and wider social and environmental implications are also of general concern. There is also a lack of data on nanomaterials on the market in the EU, since industry is not obliged to disclose any data on the effect of nano on health and the environment.

Risk assessment - It is currently not possible to extrapolate scientific data on from substances and apply it to their nano-sized version. New nanotech products therefore have to pass first a risk assessment on a case-by case basis before market authorization will be given. The scientific risk assessment on a case-by case-basis is performed by the European Food Safety Authority (EFSA) followed by a scientific opinion. EFSA was asked by the Commission to provide guidelines for the risk assessment of nanomaterials**.** The draft guidance on risk assessment concerning potential risks from applications of nanoscience and nanotechnologies to food and animal feed was endorsed for public consultation at the beginning of 2011. Stakeholders and interested parties had the opportunity to comment on the guidance, which was done by U.S. government as well.

The guidance provides practical advice on a risk assessment methodology for engineered nanomaterials used in food and feed and outlines the additional data needed for the assessment of a material when used in its nanoform to address potential intrinsic hazards that may arise. This could allow a greater regulatory certainty, but decision-making agencies rely on industry to provide high-quality information for risk assessment some of which will be considered confidential.

Need for a definition - Nanotechnologies present new challenges for the assessment and the management of risks. The European Commission proposed the use of the existing food legislation wherever possible, but the particular nature of nanotechnology requires its re-examination and revision. Existing regulations rely frequently upon parameters that may turn out to be inappropriate for certain applications of nanotechnology, such as loose nanoparticles.

Another problem is the fact that threshold values are often defined in terms of concentration or mass, for example pesticides residues levels, below which a substance may be exempt from regulation. It is still unclear how this applies to nanotechnology and to determine the relevance of such thresholds, there is an urgent need for a definition.

The Commission is under growing pressure to produce a standard EU definition for nanotechnology and materials which could be used in all legislation. The difficulty to agree on a definition is the use of a set cut-off point of a 100 nm. Although there is a general consensus around the world that the upper limit for determining whether something is nano-sized is around 100 nanometers, an upper limit of 100 nm is not sufficient from a regulatory point of view since there is no evidence that 98

nm is hazardous wile a 102 nm is not. Size needs to be just the first criterium plus a long list of other properties.

The only existing regulatory definition in the EU right now is in the cosmetics directive. The novel foods proposal, that failed to pass the conciliation procedure last month, would have included the first definition on engineered nanomaterials in the area of food in the EU. The commission promised to present a new proposal soon including elements such as a definition and labeling.

3. Regulating nano in food in the EU

As mentioned before, the current EU legislative framework covers in principle the potential health, safety and environmental risks in relation to nanomaterials but may have to be modified in the light of new information becoming available. DG Sanco has always proposed the use of the existing EU food legislation wherever possible, since it provides a good framework to cover all new applications in the food area as well as existing applications. The present legislation on food additives and novel foods already requires risk evaluation and pre-marketing notification. The ongoing revision of specific food legislation addresses explicitly the use of nanomaterials in all foods.

Currently, EU food legislation contains the following provisions on nano:

- Regulation (EC) No 1333/2008 **on Food additives** states that when "there is a significant change in the production methods or in the starting materials used" for food additives already on the Community list of approved food additives, "or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market".

- **Food Contact materials -** Regulation 450/2009 **on active and intelligent packaging** states that "new technologies to engineer substances with different chemical and physical properties than the same substances at a larger scale, for example nanoparticles, should be assessed at a case-by-case basis as regards their risk until more information is known about such new technology".

- **Food Information to Consumers (Food Labeling proposal) –** This proposal is currently going through 2nd reading and contains a provision on nano: "For products containing nanomaterials, this must be clearly indicated, using the word 'nano', in the list of ingredients".

- **Novel foods –** After failure of the novel foods proposal last month, the commission promised to come up with a new proposal containing a definition on engineered nanomaterials by the end of 2011.

Note: *Other EU legislation containing provisions on nano are the cosmetics directive, the new biocides directive, Reach and Recast.*

4. EU initiatives on nanotechnology - Political discussions between different Commission Directorates on the expected new EU strategy on nanotechnology and nanoscience are still ongoing to ensure coherence of the new strategy with recent policy developments, such as the Commission's recently published EU 2020 Strategy "Flagship Initiative on Innovation Union". The

Strategy is also likely to take into account other expected initiatives including the revision of the "EU nanotechnology Code of Conduct" and a "Communication on the regulatory aspects of nanomaterials". Once political decisions on the content of the strategy have been completed the Commission will finalize the draft which will then be sent to interservice consultation (internal discussions in the Commission before publication). The Communication could then be adopted towards the end of the second quarter of 2011.

This expected Communication would build upon the 2004 Commission communication "Towards a European Strategy for Nanotechnology" and the Commission communication "Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009". The new "Action Plan" is expected to be published as the "European Roadmap for Innovating with Nanotechnologies 2011-2015". The focus will be on innovation and safety and involvement of stakeholders in the innovation process. The aim is to achieve these objectives by using existing legal instruments and budgets and through improved cooperation with Member States, industry and other stakeholders.

5. Conclusions and next steps

- There is no straight line between products that are traditionally existing products and new applications containing engineered nanomaterials. DG Sanco is in favor of establishing a mandatory register for all nanomaterials. The Commission is pointing at the EU food industry for not revealing any information on nanotechnology applications in food. The EU food industry is trying to convince the Commission that few products are actually on the market. As such, there is an urgent need for a standardized definition. The Commission is developing an overarching "working" definition that fits with international standards and is to be adapted in individual pieces of legislation according to the nature of the different applications.

- Food applications are very sensitive to the general public, while non food nanotechnology applications are much further developed and accepted. A lack of communication to the public seems to be a major shortcoming and has a negative effect on public perception. DG Sanco is organizing an annual forum or "safety for success" dialogue to stimulate communication between different stakeholders.

- There is pro-active engagement concerning this matter from the US side and there is a lot of interest from EU side for such an approach. The **Commission** is now drafting the new Nano Action Plan 2011-2015, which will identify priorities for the development of nanotechnologies. Top priorities are safety and innovation. The report is expected the second quarter of 2011.

- **EFSA** -A final guidance document for the risk assessment of nanomaterials will be prepared once comments have been considered and EFSA has met with representatives of EU member states to discuss the draft.